

REMARKS

Claims 8-14 are currently pending in the above-identified application. Applicants submit herewith, a Declaration Under 37 C.F.R. §1.132 executed by Jacques Marie René Jan Huyghe (hereinafter "Huyghe Declaration"). In view of the following arguments, removal of the rejection and allowance of claims 8-14 is respectfully requested.

Claims 8-9 and 12-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge et al. (Artificial Organs 200, 24:174-178) in view of Pissis et al. (Proceedings of the 10th International Symposium on Electrets 1999 p. 561-564) and further in view of Young et al. (Biomaterials 1998 19:1745-1752). The Examiner states that the hydrogel taught by Malmonge requires mechanical strength and integrity. The Examiner then concludes that since both Pissis and Young teach fiber mesh reinforcement, it would have been obvious to combine the references.

Claims 8 and 10-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge in view of Pissis, and further in view of Kou et al. (J. Controlled release 12 (1990) 241-250). The Examiner states that while Malmonge does not teach the use of methacrylic acid in the hydrogel, this deficiency is satisfied by Kou.

Rejections Under 35 U.S.C. §103(a)

Malmonge et al. in view of Pissis et al. and Young et al.

Claims 8-9 and 12-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge et al. (Artificial Organs 200, 24:174-178) (hereinafter "Malmonge") in view of Pissis et al. (Proceedings of the 10th International Symposium on Electrets 1999 p. 561-564) (hereinafter "Pissis"). The Examiner contends that Malmonge teaches all aspects of the present invention with the exception of the incorporation of fibers into the hydrogel, but that this deficiency is satisfied by Pissis (Office Action page 3-4). The Examiner then concludes that it would have been obvious to combine the teachings of the references to produce a HEMA-AA hydrogel with 10% Nylon fibers (dry weight) with an AA content from 1-5% dry weight (Office Action page 4).

Applicants respectfully traverse the rejection. The recently revised Examiner guidelines for assessing obviousness set forth detailed requirements based on asserted rationales for obviousness. The Rationales To Support Rejections Under 35 U.S.C. §103 provide the following possible rationales:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods or products) in the same way;
- (D) Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See MPEP 8th Edition, rev. 6, §2141.

Applicants proceed with the understanding that this rejection conforms to rationale G quoted above. The MPEP further sets forth the requirements for an obviousness rejection under this rationale:

To reject a claim based on [rationale G], Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) a finding that there was reasonable expectation of success; and
- (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). **If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.** [emphasis added]

See MPEP 8th Edition, rev 6, §2143

The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. See MPEP 8th Edition, rev 6, § 2143

In *KSR*, the Supreme Court did not eliminate the teaching, suggestion, or motivation (TSM) test from the determination of obviousness, but rather merely opposed “a formalistic conception of the words teaching, suggestion, and motivation, or ... overemphasis on the importance of published articles and the explicit content of issued patents.” *KSR International Col. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As the Federal Circuit has subsequently explained:

[A] flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis.... The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of *evidence* – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires.

Ortho-McNeil Pharmaceutical v. Mylan, 2007-1223, *11 (Fed. Cir. Mar. 31, 2008) (emphasis added). Thus, to establish a *prima facie* case of obviousness the Examiner must show *evidence* of teaching, suggestion, or motivation to make the proposed combination of references that arose before the time of invention. Such a showing is required to guard against allegations of obviousness that are actually derived from impermissible hindsight.

In the Office Action, the only alleged teaching, suggestion, or motivation to make the proposed combination of references is that “It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the teachings of Malmonge et al. in view of Pissis et al. to produce HEMA-AA hydrogel with 10% Nylon fibers (dry weight), such that the AA content was from 1-5% (dry weight)” (Office Action page 4). However, merely rephrasing the basis of rejection provided in *KSR* fails to provide *evidence* that a person having ordinary skill in the art would combine these *particular references*. Without such an explanation, the proposed combination of references constitutes impermissible hindsight.

Malmonge describes a copolymer of HEMA and acrylic acid (AA) as artificial cartilage material. [Huyghe Declaration, paragraph 5]. The acrylic acid ionizes into acrylate and Na^+ , resulting in swelling of the HEMA-AA copolymer and improvement of the compressive strength of the cartilage material. [Huyghe Declaration, paragraph 5]. The Examples describe the presence of ionized groups in the hydrogel at a concentration of 1.8 and 3.6% (m/m). Unlike the present invention, Malmonge does not teach the presence of relatively large fibres in the

polymer gel which provide adequate strength and increased mechanical properties. [Huyghe Declaration, paragraph 9].

Applicants' invention solves the problems associated with the preparation of an artificial cartilage material which displays adequate strength and increased mechanical properties. The solution to this problem is the inclusion of fibres with lengths in the order of millimeters to reinforce the hydrogel. This results in a tissue-substituted material with increased strength and durability. As is seen in Exhibit B of the Huyghe Declaration, the fiber reinforced hydrogel of the claimed invention was compared the referenced hydrogel network. [Huyghe Declaration, paragraph 8.] Both samples were equilibrated with a physiological salt concentration. [Huyghe Declaration, paragraph 8]. After equilibration, the samples were tested under compression in a high humidity environment. [Huyghe Declaration, paragraph 8]. The use of the swellable fivers in the gel sample made in accordance with the presently claimed invention improves the toughness of the hydrogel under pressure. [Huyghe Declaration, paragraph 8] The brittle facture seen for the non-reinforced hydrogel destroyed the integrity and load-bearing capacity of the gel. [Huyghe Declaration, paragraph 8].

Pissis is directed toward the dielectric and water sorption properties of poly(hydroxyethyl acrylate) (pHEA) gel reinforced with Nylon nanoparticles. (See Title and first sentence of Introduction). [Huyghe Declaration, paragraph 6]. There is no teaching or suggestion in Pissis of the use of millimeter or greater sized fibers as this reference never contemplates improving the strength or durability of the gel. [Huyghe Declaration, paragraph 6]. At most, Pissis teaches the application of Nylon prepared by the tedious process of cutting, boiling in strong acid, and ultra sonification. [Huyghe Declaration, paragraph 6].

Moreover, paragraph [0013] of the present specification teaches the uptake of the monomer solution by the fiber, followed by polymerization of the monomers. This results in the straight formation of the polymers through the long fibre molecules. The uptake provides robust bonding of the fiber to the polymer gel matrix. This procedure produces improved anchoring and improved strength and durability of the material.

In contrast, the hydrogel taught by Pissis is prepared by the polymerization of a watery suspension of Nylon nanoparticles and a mixture of monomer/crosslinker/initiator. [Huyghe Declaration, paragraph 6]. A maximum concentration of 10% of nanoparticles (weight percentage) in the gel can be obtained before undesired agglomeration begins [See page 561, last sentence and Huyghe Declaration, paragraph 6]. It is clear that there is no uptake of the monomer solution by the nanoparticles. [Huyghe Declaration, paragraph 6]. As such, Pissis teaches away from the transverse polymerization of monomer-soaked fibres as described in the present invention where (1) agglomeration is not an issue and (2) a much higher percentage of fibre (10-70% m/m) is added. [Huyghe Declaration, paragraph 6]. Thus, one of skill in the art, with knowledge of the problems associated with agglomeration, would have no motivation to adjust the length of the nanoparticles as taught by Malmonge and Pissis. There is no teaching, suggestion, or motivation to do so because the combination teaches away from Applicants' presently claimed invention of a fibre-reinforced hydrogel comprising a concentration of 10-70% (m/m) fibres with a length of at least a millimeter. Withdrawal of the rejection is respectfully requested.

Young is an artificial skin substitute for wound dressing characterized as ultrathin (0.23nm) and containing very small amounts of fiber (<1.66%wt%). [Huyghe Declaration, paragraph 7]. Young solely discloses smooth, essentially two-dimensional ultrathin wove or knitted hydrogels, for which elastic strain rather than compressive strength is a prerequisite. [Huyghe Declaration, paragraph 9].

Therefore, neither Young nor Pissis account for the deficiencies of the teachings of Malmonge and, therefore, would not render obvious the claimed cartilage like material. For the foregoing reasons the allowance of claims 8-9 and 12-14 are not considered obvious in view of the teachings of Malmonge, Young and Pissis. Removal of the rejection and allowance of claims 8-9 and 12-14 is respectfully requested.

Malmonge et al. in view of Pissis et al. and Kou et al.

Claims 8 and 10-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge in view of Pissis and Kou et al. (Journal of Controlled Release 1990 12:241-250; hereinafter "Kou"). The Examiner characterizes Malmonge and Pissis as above. The Examiner contends that these two references do not teach the use of methacrylic acid (MA) in the hydrogel.

The Examiner states that this deficiency is satisfied by Kou. The Examiner then concludes that it would have been obvious to substitute modified hydrogel of the Malmonge-Pissis combination with that taught by Kou.

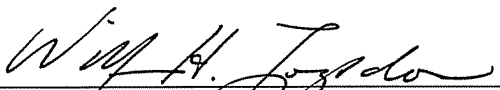
Applicants respectfully traverse the rejection. As explained in detail above, the combination of Malmonge and Pissis does not result in Applicants' currently claimed invention of a fibre-reinforced hydrogel comprising a concentration of 10-70% (m/m) fibres with a length of at least a millimeter. Kou does not resolve these deficiencies. Kou describes drug release from methacrylate-methacrylic acid polymer hydrogels. [Huyghe Declaration, paragraph 11]. There is no teaching or suggestion in Kou of the use of long fibres for the improvement of strength and durability in hydrogel compositions. [Huyghe Declaration, paragraph 11]. Kou nowhere address the problem of improving the toughness of such gels, let alone that it suggest reinforcement with long fibers for solving this problem. [Huyghe Declaration, paragraph 11]. Kou does not address the problem of improving the toughness of polymer hydrogels, not to mention, therefore Kou does not account for the deficiencies of the teachings of Malmonge and Pissis. [Huyghe Declaration, paragraph 13]. As such, the present invention is not obvious over Malmonge in view of Pissis and Kou. Applicants respectfully request withdrawal of the rejection and allowance of claims 8 and 10-11.

CONCLUSION

In view of the above remarks, reconsideration of the rejections and allowance of claims 8-14 is respectfully requested.

Respectfully submitted,

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